

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P., NAPP  
PHARMACEUTICAL GROUP LTD., BIOVAIL  
LABORATORIES INTERNATIONAL SRL, and  
ORTHO-MCNEIL, INC.,

Plaintiffs,

v.

PAR PHARMACEUTICAL, INC. and PAR  
PHARMACEUTICAL COMPANIES, INC.,

Defendants.

C.A. No. 07-255-JJF

**REDACTED  
PUBLIC VERSION**

**DEFENDANTS' OPENING BRIEF IN SUPPORT OF THEIR  
MOTION TO COMPEL PRODUCTION OF FOREIGN DOCUMENTS**

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Dated: March 25, 2008

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**NATURE AND STAGE OF THE PROCEEDING**

**A. Introduction.**

Defendants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc., (collectively “Par”) hereby move the Court, pursuant to Fed. R. Civ. P. 37 and D. Del. LR. 37.1, for an order compelling plaintiffs Purdue Pharma Products L.P. and Napp Pharmaceutical Group Ltd. (collectively “plaintiffs”) to produce:

- the foreign patent prosecution histories of the patents and patent applications corresponding to U.S. Patent No. 6,254,887 (“the patent-in-suit” or “the ‘887 patent”); and
- the non-privileged documents from foreign litigations involving plaintiffs concerning controlled-release tramadol, including documents from foreign opposition proceedings.

The requested documents are relevant to Par’s counterclaims of noninfringement and invalidity. Plaintiffs have filed patent applications pertaining to controlled-release tramadol with the same inventors throughout the world. The rejection, allowance, and withdrawal of these corresponding applications to the patent-in-suit bear on how those skilled in the art understand the claims of the ‘887 patent. Likewise, plaintiffs’ statements to foreign patent offices and inventor declarations are admissions regarding the alleged invention and the scope of the invention. It appears plaintiffs have been largely unsuccessful in patenting controlled-release tramadol in foreign jurisdictions. Par is entitled to discover why plaintiffs’ patent applications corresponding to the ‘887 patent have failed to issue, or if they have issued, what admissions were made to limit the scope of the issued patent in view of the prior art.

Initially, plaintiffs refused to produce the requested foreign prosecution and litigation documents on the ground that they were irrelevant to any claim or defense in this case. (Ex. A).<sup>1</sup> After reviewing Par's cited case law, plaintiffs subsequently changed their relevancy position. (Exs. B, C). Plaintiffs now argue that the foreign prosecution documents are equally accessible to both parties and hence, Par should independently obtain them. (Ex. C). The requested documents are not equally accessible to both parties. Moreover, the burden of obtaining these relevant documents from dozens of patent offices and courts around the world does not lie with Par. These documents are in the possession, custody, or control of plaintiffs and they should be produced from plaintiffs' files.

Plaintiffs have indicated that the file histories for the four priority applications (upon which the U.S. Application is based) were produced. Par has been unable to locate these foreign prosecution documents. Despite Par's repeated requests, plaintiffs have refused to identify the production numbers of these documents. As plaintiffs are aware, these priority applications are highly relevant to what documents will constitute prior art.

The asserted '887 patent claims at issue in this case are not entitled to the May 10, 1993 filing date of German priority application DE 43 15 525. (Ex. D, PUR0375443-0375452). The asserted claims of the '887 patent are broader than the teachings of the German priority application. (Ex. E, PUR0533352-PUR0533364). In fact, based on plaintiffs' limited production of foreign litigation documents, Par has discovered that during a New Zealand opposition proceeding initiated by Grunenthal GmbH involving a counterpart to the '887 patent, plaintiffs' patent holding company Euro-Celtique S.A. admitted that it was not entitled to the

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<sup>1</sup> Exhibits cited herein are attached to the Declaration of Robert E. Colletti in Support of Defendants' Motion to Compel Production of Foreign Documents filed contemporaneously herewith.

priority date of the Germany priority application for the same dissolution ranges as set forth in claims 1 and 19 of the '887 patent. Accordingly, if the asserted claims in the '887 patent are not entitled to the German priority date, another Euro-Celtique patent -- U.S. Patent No. 5,580,578 ("the '578 patent") -- directed to controlled-release tramadol becomes prior art. Tellingly, the '578 patent was not disclosed to the United States Patent Office during prosecution of the patent-in-suit even though it was simultaneously pending. More troubling is that the same attorney who prosecuted the patent-in-suit also prosecuted the undisclosed '578 patent.

A limited production of foreign prosecution and litigation documents has been made to date. It is impossible to determine the full extent of plaintiffs' admissions about the alleged invention and how the patentees interpreted the scope of their patents before litigation. As such, plaintiffs should produce the requested foreign prosecution and litigation documents in their entirety.

**B. Background And Proceedings To Date.**

This action is based on Par's filing of Abbreviated New Drug Application ("ANDA") No. 78-783 with the U.S. Food and Drug Administration ("FDA"). Par seeks FDA approval to market a generic version of Biovail's tramadol hydrochloride extended-release tablets, which Ortho-McNeil, Inc. and Purdue Pharma Products L.P. market under the brand name Ultram ER for the management of moderate to moderately severe chronic pain. Plaintiffs have brought this action alleging that the commercial sale of Par's proposed product as described in Par's ANDA No. 78-783 would infringe claims 1 and 19 of U.S. Patent No. 6,254,887 ("the '887 patent").

The '887 patent issued on July 3, 2001 to Euro-Celtique S.A. ("Euro-Celtique"), a patent holding company for Purdue, Napp, and Mundipharma, on assignment from the eight inventors identified on the face of the patent. In May 2007, Mundipharma GmbH, Napp Pharmaceutical Group Limited, Napp Research Centre Limited, Mundipharma AG, and Euro-Celtique executed

assignments of the '887 patent to Napp Pharmaceutical Group Limited and Purdue Pharma Products L.P. (Ex. F).

Discovery is underway. Both parties have served document requests and interrogatories. Par has taken a deposition of Davidson, Davidson & Kappel LLC, the law firm that prosecuted the patent-in-suit and fact depositions are being scheduled in the United States, Germany, and England. Par is also seeking documents from non-party Grunenthal USA Inc. and a deposition and documents from Grunenthal GmbH in Germany, through a letter of request pursuant to the Hague Convention. (D.I. 48). Fact discovery is scheduled to close on May 15, 2008. (D.I. 23). A pretrial conference is scheduled for October 16, 2008. (D.I. 23).

### **SUMMARY OF THE ARGUMENT**

Plaintiffs are withholding relevant, properly discoverable documents. The withheld documents include foreign prosecution documents corresponding to the '887 patent and files concerning the litigation of controlled-release tramadol abroad. These documents were initially requested from plaintiffs in Par's August 20, 2007 document requests pursuant to Fed. R. Civ. P. 34. (D.I. 13). Despite the approximately 1.5 million pages produced by plaintiffs, many of these key documents have been withheld.

#### **A. Foreign Prosecution Histories.**

The requested foreign documents are relevant to this case because statements made about the alleged invention to foreign patent offices show how the patentees' understood the invention prior to litigation. Also, the prior art references that foreign patent offices have cited bear directly on the validity of the '887 patent. Apparently, only a few foreign applications pertaining to controlled-release tramadol have issued as patents. Foreign patent applications corresponding to the '887 patent have been withdrawn, contested, or are still pending. Par is certainly entitled to learn why corresponding patent applications pertaining to extended-release tramadol were

withdrawn or rejected by foreign patent offices, and why only a small percentage issued. Such information is relevant to Par's noninfringement and invalidity counterclaims in this case.

Plaintiffs agree that at least the four priority documents (three UK and a German patent application) listed on the face of the patent-in-suit are relevant to this case. (Ex. C). As such, plaintiffs should be required to produce these prosecution histories, or if they have been produced, identify their production numbers. For example, German priority application DE 43 15 525 ("the '525 priority application"), filed on May 10, 1993, to which the '887 claims priority, has not issued as a patent. It apparently has a long history of prosecution in the German Patent Office and courts. Yet documents pertaining to this history have not been produced.

The status of the German priority application goes to central issues in this case. Specifically, the '525 priority application discloses examples of *in vitro* dissolution rates of 39%, 35%, and 43% tramadol released after one hour. The *in vitro* dissolution ranges of at least claims 1, 3-6, 13, 15-20, 22-27, 29, 31-32 of the '887 patent are broader than, and thus unsupported by, the *in vitro* dissolution ranges stated in and set forth in the examples in the '525 priority application. The foreign priority applications and prosecution histories are relevant to determine which claims, if any, are entitled to priority date earlier than the filing date of the '887 patent. Likewise, the prosecution histories for patent applications that have not issued due to withdrawal, refusal, or cancellation should be produced because Par is entitled to learn if the applications were rejected for validity reasons that would be applicable to the '887 patent under U.S. law.

**B. Foreign Litigation Pertaining To Controlled-Release Tramadol.**

Plaintiffs should produce court decisions and evidence submitted in foreign litigations and opposition proceedings concerning controlled-release tramadol. These documents contain admissions by plaintiffs and factual findings and rulings by the courts. **REDACTED**



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Moreover, documents produced by plaintiffs indicate there was a Chilean opposition proceeding (Ex. H, PUR0536000), Australian opposition proceeding (Ex. I, PUR0912025), and a New Zealand opposition proceeding (Ex. J, NAPP0267588-NAPP0267600) involving controlled-release tramadol. The non-privileged documents from plaintiffs' litigation and opposition proceeding files should be produced, as arguments made, positions taken, and decisions rendered before foreign courts are relevant to this case.

For example, based on plaintiffs' limited and incomplete production of foreign litigation documents, Par has determined that during Grunenthal GmbH's ("Grunenthal") opposition to plaintiffs' New Zealand Patent Application No. 260408, Plaintiffs admitted they were not entitled to the May 10, 1993 German priority date. Plaintiffs' patent holding company, Euro-Celtique, stated: "Claim 34 clearly takes the first priority date of 10 May 1993, and *in general the remaining claims take the third date of 09 March 1994*" (Ex. J, NAPP0267590) (emphasis added). Claim 1 of the New Zealand patent application has the same *in vitro* dissolution ranges as claims 1 and 19 of the '887 patent asserted in this case. Euro-Celtique's admission on February 26, 1997 that claim 1 of the New Zealand patent application is not entitled to the priority date of May 10, 1993 is significant because this admission applies to claims 1 and 19 of the '887 patent, which have the same dissolution ranges.

As another example, plaintiffs should produce documents from the German litigation *In re Temmler Pharma GmbH v. Euro-Celtique SA*. The District Court of Dusseldorf found Temmler's "TRAMADOLOR long" controlled-release tramadol product fell outside the scope of plaintiffs' corresponding EP 624 366 patent claims. Yet, plaintiffs have not produced documents

from that case. Documents from this and other litigations are certainly relevant to the noninfringement and invalidity issues in this case. Also, like in the New Zealand opposition proceeding, there may be significant limiting admissions made by plaintiffs that should apply to this case. All of plaintiffs' non-privileged documents, including Euro-Celtique's non-privileged documents, concerning foreign litigation and opposition proceedings for controlled-release tramadol should be produced.

### **STATEMENT OF FACTS**

#### **A. Par's Production Requests For The Withheld Documents.**

On August 20, 2007, Par served production requests on each of the four plaintiffs. (D.I. 13). The requests asked each plaintiff to produce foreign prosecution histories and foreign litigation documents corresponding to the patent-in-suit. The requests are set forth below:

#### **Production Request No. 6**

All documents concerning the preparation and prosecution of the patent-in-suit or any foreign counterpart.

#### **Production Request No. 7**

Any initial or preliminary draft of any patent application for the patent-in-suit or any foreign counterpart, including but not limited to a draft of any portion of the written description or the claims.

#### **Production Request No. 13**

All documents concerning any foreign counterpart application (including but not limited to an international or PCT application) of any U.S. patent application for the patent-in-suit.

#### **Production Request No. 14**

All references cited during the prosecution of any foreign counterpart of the U.S. patent applications for the patent-in-suit.

**Production Request No. 15**

All documents including but not limited to correspondence, patent office filings, judicial or regulatory filings concerning any foreign counterpart of any U.S. patent application for the patent-in-suit.

**Production Request No. 40**

All documents concerning communications or agreements between [Purdue, Napp, Biovail or Ortho-McNeil] and any third party regarding the validity or infringement of the patent-in-suit or any foreign counterpart, including but not limited to correspondence and court or administrative documents.

**Production Request No. 42**

All documents concerning any conflict, opposition, nullity, or infringement proceeding in the United States or any foreign country concerning the patent-in-suit or their foreign counterparts, including, but not limited to all pleadings, exhibits, affidavits, affidavit exhibits, and supporting data, trial testimony, documents, and things produced in such matters, and any decision by the appropriate tribunal.

**Production Request No. 43**

All documents concerning any litigation or adversarial proceeding involving the patent-in-suit or any of foreign counterparts, including but not limited to court or agency filings and orders.

**Production Request No. 45**

All transcripts and exhibits from each deposition or other sworn statement provided by a [Purdue, Napp, Biovail or Ortho-McNeil] employee, [Purdue, Napp, Biovail or Ortho-McNeil] witness, or third party witness represented by [Purdue, Napp, Biovail or Ortho-McNeil] counsel in connection with any litigation, opposition, or adversarial proceeding involving the patent-in-suit or any foreign counterparts.

**Production Request No. 46**

All correspondence between [Purdue, Napp, Biovail or Ortho-McNeil] and any third party and/or between their counsel in any litigation, opposition, or adversarial proceeding involving the patent-in-suit or any foreign counterparts.

**B. Par's Efforts To Obtain The Requested Documents.**

Upon reviewing plaintiffs' document production, it became apparent that the full-breadth of the requested foreign prosecution documents and foreign litigation documents was not

produced. Par identified plaintiffs' production deficiencies and requested the withheld documents in its letters of February 5, 11, and 21. (Exs. K, L, M). Three weeks after Par's initial letter, plaintiffs took the position that the requested foreign prosecution histories and foreign litigation documents are not relevant to any claim or defense in this case. (Ex. A). Par then cited case law supporting its position that the requested documents are relevant and should be produced. (Ex. B). Par also requested that plaintiffs identify the production range for the prosecution histories of the priority documents listed on the face of the patent-in-suit, if in fact they were produced. (Ex. B).

During the March 5, 2008 deposition of Davidson, Davidson & Kappel, Par's counsel informed plaintiffs' counsel that the requested documents still had not been produced. Par requested plaintiffs' position on the withheld documents. Plaintiffs responded two days later and again refused to produce the requested documents by stating that the production of such documents is overly burdensome and the documents are equally accessible to both parties. (Ex. C). Plaintiffs failed to identify the production ranges for the prosecution histories of the priority documents listed on the face of the patent-in-suit as requested by Par. (Ex. C).

### ARGUMENT

Federal Rule of Civil Procedure 26(b)(1) provides that a party "may obtain discovery regarding *any nonprivilege matter* that is relevant to any party's claim or defense." Fed. R. Civ. P. 26(b)(1) (emphasis added); *see also Pacitti by Pacitti v. Macy's*, 193 F.3d 766, 777 (3d Cir. 1999) (stating that "it is well recognized that the federal rules allow broad and liberal discovery."). Under the relevancy standard, "[r]elevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1). Where, as here, a party fails to produce documents, the court may compel production of the requested discovery. Fed. R. Civ. P. 37(a)(2)(b); *see, e.g.*,

*Royal Indemnity Co v Pepper Hamilton LLP*, 479 F. Supp. 2d 419 (D. Del. 2007) (granting party's motion to compel discovery).

**A. The Requested Documents Are Relevant And Should Be Produced.**

Contrary to plaintiffs' position in their February 27, 2008 letter, the foreign patent prosecution histories corresponding to the patent-in-suit and the foreign litigation documents related to controlled-release tramadol are relevant to this case.

**1. The Foreign Patent Prosecution Histories Are Relevant.**

The requested foreign prosecution histories are properly discoverable in this case and directly relate to counterclaims of noninfringement and invalidity of the patent-in-suit. The Federal Circuit has expressly acknowledged the relevance of evidence from foreign patent offices. *See Caterpillar Tractor Co. v Berco, SpA*, 714 F.2d 1110, 1116 (Fed. Cir. 1983) (“[W]hen such matters [instructions to foreign counsel and a representation to foreign patent offices] comprise relevant evidence they must be considered.”); *see also Tanabe Seiyaku Co., Ltd v U.S. Int’l Trade Comm’n*, 109 F.3d 726, 733 (Fed. Cir. 1997) (“representations made to foreign patent offices are relevant to determine whether a person skilled in the art would consider butanone or other ketones to be interchangeable with acetone in [the patentee’s] claimed N-alkylation reaction”). This Court denied a motion to exclude a decision of the Austrian Patent Office and held: “Because the Court cannot conclude that this evidence is entirely irrelevant, and Pfizer has not advanced any grounds under *Rule 403* justifying its exclusion, the Court will admit the evidence and address Pfizer’s concerns in terms of the weight to be afforded this evidence.” *Pfizer Inc v Ranbaxy Labs, Ltd*, No. 03-209, 2005 U.S. Dist. LEXIS 34901, at \*11 (D. Del. Dec. 22, 2005). Likewise, in *Liposome Co v Vestar, Inc.*, No. 92-332, 1994 U.S. Dist. LEXIS 19325, at \*40 (D. Del. Dec. 20, 1994), the Court held that statements made to a foreign Patent Office are relevant as evidence of how the patentees “had in fact read the words of the

claim at a time when it was not looking at them as a necessary step in building a claim for relief that moves from complaint to recovery. [Patentee's] prior statements are also relevant as they are evidence of how one skilled in the art would interpret the words in the patent."

Plaintiffs' statements regarding controlled-release tramadol to foreign patent offices will shed light on prior art and the patentees' understanding of the scope of the alleged invention prior to this litigation. For example,

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751 has been refused, and patent application HU 9401478 has been cancelled. (Ex. N). Par is entitled to know why these patent applications corresponding to the '887 patent were revoked, cancelled, rejected, or withdrawn. On the other hand, Par is also entitled to plaintiffs' statements in prosecution histories for patents that issued. These statements may have defined the alleged invention over prior art hence enabling the issuance of a patent from a foreign patent office.

A further example of the relevance of the foreign prosecution histories relates to the date upon which the U.S. application is allowed to claim priority. German priority application DE 43 15 525, filed on May 10, 1993, to which the '887 claims priority, has not issued. The prosecution history for this application cannot be located in plaintiffs' production. The status of this application goes to central issues in this case. Specifically, the '525 priority application discloses examples of *in vitro* dissolution rates of 39%, 35%, and 43% tramadol released after one hour. The broadest *in vitro* dissolution rate ranges stated in the German '525 priority application, when measured by USP Paddle Method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 nm, are between 5 and 50% (by weight) tramadol released after 1 hour, between 10 and 75% (by weight) tramadol released after 2 hours, between 20 and 95% (by weight) tramadol released after 4 hours, between 40 and 100% (by weight)

tramadol released after 8 hours, more than 50% (by weight) tramadol released after 12 hours, more than 70% (by weight) tramadol released after 18 hours and more than 80% (by weight) tramadol released after 24 hours. The *in vitro* dissolution ranges of at least claims 1, 3-6, 13, 15-20, 22-27, 29, 31-32 of the '887 patent are broader than, and thus unsupported by, the broadest *in vitro* dissolution ranges stated in the German '525 priority application. The German '525 priority application and prosecution history are relevant to determine which claims, if any, are entitled to priority date earlier than the filing date of the '887 patent, and to determine what constitutes prior art for invalidity purposes. Moreover, it is currently unknown to Par what other information will be found in the prosecution histories of the corresponding foreign patent applications. Nevertheless, the requested documents are relevant and discoverable.

## 2. The Foreign Litigation Documents Are Relevant.

The requested documents from foreign litigation involving patents or applications corresponding to the patent-in-suit are also relevant. Foreign controlled-release tramadol litigations focused on the same issues contested in this case. Plaintiffs cannot simply ignore litigation involving controlled release tramadol in foreign jurisdictions. See *Vas-Cath Inc. v. Mahurkar*, 745 F. Supp. 517, 526 (N.D. Ill. 1990), *rev'd on other grounds*, 935 F.2d 1555 (Fed. Cir. 1991) ("I do not read the Federal Circuit's cases as compelling courts of the United States to ignore informed decision rendered abroad . . . . If a foreign court renders judgment on a question of fact with significance in each system of law, there is no reason not to take over that decision . . . ."). As such, the evidence submitted by plaintiffs in foreign litigations and the decisions of foreign courts concerning the foreign counterparts to the '887 patent are relevant and properly discoverable in this proceeding.

Significantly, Napp produced a document entitled "COUNTER STATEMENT," from a Grunenthal GmbH opposition to Euro-Celtique's New Zealand patent application, which



corresponds to the patent-in-suit. During Grunenthal's opposition, Euro-Celtique made an important admission concerning the priority dates of the claims. Specifically, Euro-Celtique stated: "Claim 34 clearly takes the first priority date of 10 May 1993, and *in general the remaining claims take the third date of 09 March 1994*" (Ex. J, NAPP0267590) (emphasis added). Claim 1 of New Zealand patent application No. 260408 claims the same dissolution rate ranges as set forth in claims 1 and 19 of the '887 patent, which have been asserted against Par. Claim 34, on the other hand, sets forth a narrower dissolution range that is identified in the May 10, 1993 patent application. The New Zealand patent application, and other documents from this file, do not appear to have been produced. If Euro-Celtique, or plaintiffs, made other limiting representations to courts, Par should be entitled to review those admissions. Moreover, Par is entitled to learn the outcome and reasoning set forth by the New Zealand court in this case.

Plaintiffs should also produce documents from the German litigation *In re Temmler Pharma GmbH v Euro-Celtique SA*. Par is aware that the District Court of Dusseldorf found Temmler's "TRAMADOLOR long" controlled-release tramadol product did not infringe plaintiffs' '366 patent claims. The court's reasons for finding no infringement and the documents relied upon are relevant to this case. Documents showing what plaintiffs told foreign courts about the patents corresponding to the '887 patent are relevant, and should be produced.

During prosecution of the '887 patent, the PTO required the prosecuting attorney to submit evidence from foreign litigations. According to plaintiffs' counsel:

In addition to the foreign applications that form the basis of the U.S. patent-in-suit, there have been at least four foreign litigations and foreign opposing proceedings involving at least seven opposers relating to other Purdue/Napp/Mundipharma applications relating to controlled-release tramadol. During prosecution of the U.S. patent-in-suit, DDK disclosed these proceedings to the U.S. Patent and Trademark Office and provided evidence submitted in those proceedings to the PTO. These documents include art



references, expert reports and affidavits submitted by Dr. Momberger, Prof. Florence, Ms. Malkowska, Dr. Fell, Dr. Posch, Dr. Beszedes, Dr. Budd, Mr. Oshlack, Dr. Roth, Dr. Winkler, and Dr. Smith, and other papers submitted by Napp, Asta Medica Group, Lannacher Heilmittel, Hexal, Arzneimittelwerk Dresden, Krewel Meuselbach, and Nycomed Danmark. All of these have been produced to Par.

(Ex. C). It appears that the documents identified in the quote above from foreign litigations that were submitted to the PTO had been produced. Regardless, Par should not be limited in its discovery to what plaintiffs' prosecuting attorney decided was material to the prosecution of the application that issued as the '887 patent. Instead, Par should be entitled to consider the foreign litigation documents in their entirety and review all properly discoverable information.

**B. The Requested Documents Are In the Possession, Custody, Or Control Of Plaintiffs.**

Fed. R. Civ. P. 34 requires a party to produce documents in its possession, custody or control. The word "control" is broadly construed for discovery purposes. *Playboy Entertainment Group, Inc v. United States*, No. 96-94, 1997 U.S. Dist. LEXIS 22297, at \*9 (D. Del. Dec. 11, 1997). Here, the requested foreign prosecution documents should be in the possession, custody or control of plaintiffs. Euro-Celtique is the patent holding company for Napp, Purdue, and Mundipharma. As the assignee of many foreign patent applications corresponding to the '887 patent and the named litigant in several opposition proceedings, Euro-Celtique should produce the foreign prosecution and litigation documents corresponding to the patent in suit. At a minimum, plaintiffs should have control over their patent holding company's files.

**C. The Requested Documents Are Not Equally Accessible To Both Parties.**

The requested documents are not equally accessible to both Par and plaintiffs. In fact, many of the foreign patent applications corresponding to the patent-in-suit never issued. For

example, DE 43 15 525, filed on May 10, 1993 and to which the '887 claims priority, has not issued and its prosecution history is not publicly available. It would be overly burdensome for Par to pursue obtaining documents from approximately 30 patent offices around the world, where on the other hand, the requested documents should be centrally located in plaintiffs' files. (Ex. J, DDK1319-DDK13922). Moreover, Par should not be limited to select documents from foreign proceedings that plaintiffs decided to submit to the U.S. Patent Office during prosecution of the '887 patent. The requested documents can and should be produced by plaintiffs in their entirety.

### CONCLUSION

For the foregoing reasons, Par respectfully requests that the Court order plaintiffs to (1) produce the foreign prosecution histories corresponding to the patent-in-suit; (2) produce the non-privileged documents from the foreign litigations and opposition proceedings involving plaintiffs (including Euro-Celtique and Mundipharma) related to controlled-release tramadol; and (3) identify the production numbers of the prosecution histories for the foreign priority documents identified on the face of the patent-in-suit.

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IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I hereby certify that on March 25, 2008, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing(s) and Hand Delivered to the following:

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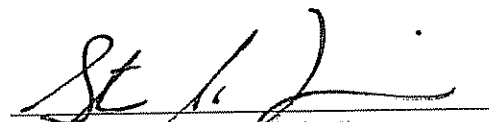
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**IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF DELAWARE**

**CERTIFICATE OF SERVICE**

I hereby certify that on April 8, 2008, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing(s) and Hand Delivered to the following:

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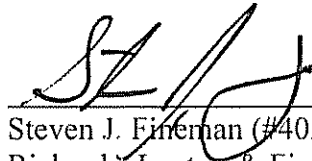
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